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510(k) Summary of Safety and Effectiveness

Date: May 29, 2008

Submitter: National Advanced Endoscopy Devices, Inc.
22134 Sherman Way
Canoga Park, CA 91303
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Contact Person: Gayle M. Butler
Compliance Manager

Product:
Trade Name: AED Bipolar Forceps
Classification: Class II
Common Name: Bipolar Forceps
Classification Name: Device, Electrosurgical Cutting & Coagulation & Accessories (GEI, 21 CFR 878.4400)

Predicate Devices: Bipolar Forceps, Richard Wolf Medical Instruments, Corp. **K023813**
Stryker Endoscopic Instruments and Accessories, Stryker Endoscopy, **K935237**

Device Description: **AED Bipolar Forceps** consist of
- Standard insulated bipolar handles
- Outer shaft with insulated tip
- Jaw inserts (forceps, scissors)

The device is reusable and provided non-sterile. The device must be cleaned and sterilized before use. All forceps are of the same basic design with differences in tip configurations.

Intended Use: **AED Bipolar Forceps** are reusable devices (bipolar forceps/scissors and electrodes) that facilitate grasping, cutting and manipulation of soft tissue during laparoscopic procedures with the use of high frequency electrical current (bipolar electrocautery). **AED Bipolar Forceps** have not been shown to be effective for tubal sterilization or tubal ligation/coagulation for sterilization procedures. Do not use these bipolar forceps for these procedures.

Comparison to Predicate Device: Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the predicate devices cited and raise no new issues of safety and effectiveness.

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Performance Standards: **AED Bipolar Forceps**

IEC 60601 -2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (Fourth Edition, 2006).

ISO 14937:2000 Sterilization of health care products – General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.

Conclusion: Based on the technical information provided, intended use and performance information provided in this premarket notification, **AED Bipolar Forceps** have been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2008

National Advanced Endoscopy Devices, Inc.
c/o Gayle M. Butler
22134 Sherman Way
Canoga Park, CA 91303

Re: K081553
Trade/Device Name: AED Bipolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 26, 2008
Received: August 29, 2008

Dear Ms. Butler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number (if known): K081553

Device Name: AED Bipolar Forceps

Indications for Use:

AED Bipolar Forceps are reusable devices (bipolar forceps/scissors and electrodes) that facilitate grasping, cutting and manipulation of soft tissue during laparoscopic procedures with the use of high frequency electrical current (bipolar electrocautery). **AED Bipolar Forceps** have not been shown to be effective for tubal sterilization or tubal ligation/coagulation for sterilization procedures. Do not use these bipolar forceps for these procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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